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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/603,819	06/26/2003	Thomas Nilsson	239639US8	2765

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EXAMINER	
ALSTRUM ACEVEDO, JAMES HENRY	
ART UNIT	**PAPER NUMBER**
1616	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/03/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/603,819	NILSSON ET AL.	
	Examiner	Art Unit	
	James H. Alstrum-Acevedo	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/16/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 21-42 are pending. Claims 21, 25-28, 30-31, and 33-38 have been amended. Claims 40-42 are new. Receipt and consideration of Applicants' arguments, remarks, and amendments filed on September 27, 2006 is acknowledged.

Specification

The objection to the disclosure because of the following informality: the title of the disclosure on page 1 is missing the letter "o" in the word "administration" **is maintained**, because the missing letter in the title has not been corrected.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 21-38 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement **is withdrawn** per Applicants' amendments removing new matter.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of claims 21-24, 26, 31, 33, 35, and 38 under 35 U.S.C. 102(b) as being anticipated by Haikarainen et al. (WO 00/64519) **is withdrawn** per Applicants' claim amendments requiring that the medical product be sealed with a protective foil.

Response to Arguments

Applicant's arguments, see page 12, filed September 27, 2006 with respect to claims 21-24, 26, 31, 33, 35, and 38 have been fully considered and are persuasive. The rejection of claims 21-24, 26, 31, 33, 35, and 38 under 35 U.S.C. 102(b) as being anticipated by Haikarainen et al. (WO 00/64519) has been withdrawn.

The rejection of claims 21-26, 30-35, and 37-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Davies et al. (US 2002/005344 A1) **is maintained** for the reasons of record, described on pages 6-8 of the office action mailed on 1/12/2006; articulated on page 10 of the office action mailed on 6/28/2006; and further articulated below. New claims 39-40 and 41-42 are appended to this rejection, per the disclosures of Davies set forth in the office action mailed 1/12/2006 and in [0094]. **In summary, claims 21-26, 30-35, and 37-42 are rejected under 35 U.S.C. 102(b) as being anticipated by Davies et al. (US 2002/005344 A1).**

Response to Arguments

Applicant's arguments filed September 27, 2006 have been fully considered but they are not persuasive. Applicants traverse this rejection by arguing that Davies does not allegedly disclose a separate depositing of pre-metered powder quantities onto at least one target area of a

dose bed, because the at least two active agents are mixed together and provided in a single dose pocket as taught by Davies. The Examiner respectfully disagrees, because Applicants' claim language does not preclude the combination of medicaments. It merely requires that each medicament is "deposited separately onto at least one target area of a dose bed", which to an ordinary skilled artisan would reasonably mean (1) deposition at different points in time (i.e. not simultaneously deposited) onto the same target area (e.g. same dose pocket) or (2) deposition in such a manner that the two medicaments do not occupy the same space on the same target area. Davies satisfies both of these reasonable interpretations of the phrase "deposited separately onto at least one target area of a dose bed" because (1) deposition at two different times of two different drugs onto the same target area (e.g. same dose pocket) inherently results in a mixture of two medicaments and (2) there is nothing in the prior art to indicate that these medicaments would form complexes and it is physically impossible for two medicaments to occupy the same space, therefore two medicaments deposited onto the same target area (e.g. same dose pocket) are inherently separately deposited.

The rejection of claims 21-24, 26-33, and 36-38 under 35 U.S.C. 102(b) as being anticipated by Clarke et al. (US 2002/0103260) **is maintained** for the reasons of record set forth on pages 8-9 of the office action mailed on 1/12/2006; articulated on pages 10-11 of the office action mailed on 6/28/2006; and further articulated below. New claims 39-42 are appended to this rejection per the teachings set forth on pages 8-9 of the office action mailed on 1/12/2006. In summary, **claims 21-24, 26-33, and 36-42 are rejected under 35 U.S.C. 102(b) as being anticipated by Clarke et al. (US 2002/0103260).**

Response to Arguments

Applicant's arguments filed September 27, 2006 have been fully considered but they are not persuasive. Applicants' traversal arguments are based on Applicants unfounded assertion that the smaller medicament particles of formoterol fumarate and fluticasone propionate taught by Clarke would adhere to the larger lactose particle surface and interact. Argument in the absence of evidence is unpersuasive. Applicants have provided no evidence or data to suggest that (1) the medicaments would adhere to the lactose surface and (2) even if one were to give Applicants the benefit of the doubt and assume that the drug particles adhered to the carrier surface, Applicants have not provided evidence to support their assertion that these medicaments particles would inherently detrimentally interact.

Double Patenting

Applicant is advised that should claims 21 and 31 be found allowable, claims 39 and 40 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Both claims 21 and 39 recite, the same step of separately depositing the pre-metered powder quantity per medicament onto a common target area of the dose bed. Similarly, both claims 31 and 40 recite that the metered combined dose comprises quantities of at least two medicaments, separately deposited on a common target area of the dose bed.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The provisional rejections on the ground of nonstatutory obviousness-type double patenting cited on pages 14-19 of the office action mailed on 1/12/06 and maintained on page 11 of the office action mailed on 6/28/06 (i.e. rejections over copending applications: 10/703,505; 10/728,986; 10/870,907; 10/870,909; 10/870,945; 10/921,192; 11/085,523; 11/049,696; 11/111,888; and 11/272,859) **are maintained** for the reasons of record and because Applicants have not provided any substantive arguments.

Response to Arguments

Applicant's arguments filed September 27, 2006 have been fully considered but they are not persuasive. Applicants have not provided any substantive arguments and have only requested that the instant claims be allowed to issue first before consideration of the possibility

of double patenting with the cited copending applications. This is not persuasive, because the instant claims are not in condition for allowance.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Biggadike et al. (US 2005/0175545); Clark et al. (US 2005/0103678); and Chawla (WO 98/26828) are considered relevant because these references teach dry powder medicaments in medical products sealed with protective foils and designed from moisture impermeable materials (e.g. Clark).

Claims 21-42 are rejected. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner can normally be reached on M-F, 9:00-6:30, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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